



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Tetutoshi Mithiue, Shyouiti Fujii, Takashi Doi, and Takeshi Okamoto

Serial No. : 10/089,325 Confirmation No. 1360

Filed : July 12, 2002

REMARKS

In the Office Action mailed April 19, 2005, the Examiner objected to the drawings under 37 CFR 1.83(a) because the liquid drip prevention mechanism and the non-return means are features in the claims but not shown in the drawings. Applicant respectfully points out that the liquid drip prevention mechanism is shown as reference 216 in Fig. 12 and as reference 218 in Fig. 14 (a) to (c). In the specification, such mechanism is described on page 19, lines 22 to page 20 line 1, and page 20, lines 2-4. The non-return means is shown in FIG. 6, and defined in the specification on page 17, lines 1-5. Applicant amends the specification herein to more clearly describe these features with respect to the drawings. Thus, applicant respectfully states that the drawings show every feature of the invention specified in the claims and that no changes to the drawings are needed. No new matter has been added.

Claims Objections

The Examiner objected to claim 30 because it is a duplicate of claim 21. Applicant herein amends claim 30 to depend from claim 11; this was an inadvertent error in the earlier amendment. No new matter has been added.

In addition, applicant adds new claims 31 to 33 corresponding to original claims 22, 24 and 25, respectively. No new matter has been added.

Claims Rejections - 35 USC §112

The Examiner has rejected claims 10 and 27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant herein cancels claims 10 and 27 and respectfully requests this rejection be withdrawn.

Claims Rejections - 35 USC §103

The Examiner has rejected claims 1-10, 19-26, 28 and 30 under 35 U.S.C. 103(a) as being unpatentable over Suyoeoka et al., U.S. Patent No. 3,595,230 in view of Schoenberg, U.S. Patent No. 4,888,001. The Examiner states that Suyoeoka et al. teaches the features of applicant's invention except for the pair of flexible wings. The Examiner states that Schoenberg discloses a needle injector with a pair of flexible wings, and the Examiner concludes that it would have been obvious to one of ordinary skill in the art, at the time of the invention, to combine Suyoeoka et al. with Schoenberg because Schoenberg taught the advantage of having wings, which are for easier manipulation of the needle device as well as a safety precaution during and after injecting.

Applicant respectfully traverses this rejection. Applicant herein cancels claims 1-10, 19, 22, 24, 25, 27 and 28. Applicant amends claim 11 to more clearly define the invention by claiming in one claim the features of original claims 11, 13 and 14; also, applicant amends claims 20 and 21 to depend from claim 11. Specifically, applicant adds that in addition to the lumen of the needle housing member having enlargement and constriction units, the exterior of the needle housing member reflects the structure of the lumen and contains enlargement and construction units also. Support for this amendment can be found in the drawings, see Figures 2, 3, 5 and 9. Thus claims 20, 21, 23 and 30 depend from claim 11 which was not cited by the Examiner as being made obvious from Suyoeoka et al. with Schoenberg.

By contrast, Suyoeoka et al. discloses a “... tubular sheath with slots which slots receive fins attached to a needle and catheter...”. The fins are grasped to move the needle, and a series of slots lock the needle into place, allowing advancement of the catheter. The interaction of the fins and slots lock the needle in place in the sheath, so that the catheter can advance until it is completely free of the sheath and the needle. (‘230, Column 1, lines 63-73). Applicant's invention has neither fins nor slots for receiving fins; instead, the hub can be displaced by sliding within the lumen of the hollow needle-housing member, and the upper part of the hub, which has an arced curved shape in the axial direction and a middle part which has the largest diameter in the axial direction, can be retained by being housed in the lumen.

Further, applicant's invention has a hollow needle-housing member formed preferably from a flexible material, while Suyeoka et al. discloses a flexible but rigid sheath. Also, Suyeoka et al., does not disclose or teach an arced curved shape sheath.

Thus Suyeoka et al. discloses a more complex mechanism, requiring fins and slots for receiving the fins. Applicant's invention is an improvement over this prior art, requiring fewer pieces or parts, being less costly to manufacture and to assemble. Also, applicant's invention can be more durable, since it does not have fins which could bend or break, preventing the fins from being received and retained by the slots.

Applicant's amended claim 11 is patentably distinct from Suyeoka et al., which does not teach or disclose a needle housing member whose exterior walls enlarge and constrict, reflecting the enlarging and constricting of the interior of the needle housing member. This feature is not found in other prior art cited by the Examiner. Thus, Suyeoka et al. combined with any reference would not teach or anticipate applicant's invention. Applicant respectfully requests that the rejection of claims 20, 21, 23 and 30, all of which now depend from claim 11, be withdrawn.

Claims Rejections - 35 USC §103

The Examiner has rejected claims 11-18, 27, 28 and 29 under 35 U.S.C. 103(a) as being unpatentable over Dillon et al., U.S. Patent No. 5,833,670 in view of Schoenberg, U.S. Patent No. 4,888,001. The Examiner states that Dillon et al. teaches the features of applicant's invention except for the pair of flexible wings. The Examiner states that Schoenberg discloses a needle injector with a pair of flexible wings, and the Examiner concludes that it would have been obvious to one of ordinary skill in the art, at the time of the invention, to combine Dillon et al. with Schoenberg because Schoenberg taught the advantage of having wings, which are for easier manipulation of the needle device as well as a safety precaution during and after injecting.

Applicant respectfully traverses this rejection. Applicant cancels claims 12-15, and 27-28, and herein amends claim 11 as described above. Claims 16-18 and 29 depend from amended claim 11. Applicant's invention includes a hollow needle-housing member including at least "two expanded parts [] spaced via a reduced diameter part" (emphasis added, see (4), amended

claim 11). Applicant's invention in its preferred embodiment has expanded parts (202, 204) for both latching and moving the hub shaft in concert with the reduced diameter part that is formed between the expanded parts. These parts can house at least one portion, and preferably the whole, of the upper face of the hub shaft. Further, because of the specific shape of the hub as claimed, the length of the hub axial can be shortened, so that the size of the injection needle can be minimized which facilitates setting of the wings on the skin and simplifies the use of the device. In addition, the needle housing members do not need to be completely identical, because of the flexibility of the expanded parts. Combined with the simple, partly spherical shape of the hub, these features enable the present invention to be manufactured more easily and less expensively than prior art.

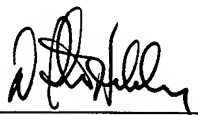
By contrast, Dillion et al. includes restraining means (16) and fixing means (8) in the form of resilient barbs, for cooperating with the needle mount to fix and restrain the sleeve member (column 3, lines 22-26). No expanded or reduced diameter parts are disclosed or taught in Dillion et al., instead a rectangular box with curved top and bottom are disclosed and claimed. Thus Dillion et al. combined with any reference would not teach or anticipate applicant's invention. Applicant respectfully requests that the rejection of claims 11, 15-18, and 29 be withdrawn.

It is respectfully submitted that the application is now in condition for allowance, and such action is requested. No new matter has been added. The examiner is invited to telephone the undersigned if there are any matters which could be discussed to expedite the prosecution of the above-identified application.

Respectfully submitted,

Date: August 18, 2005
DPH/KRV

D. PETER HOCHBERG CO., L.P.A.
1940 East 6th Street - 6th Floor
Cleveland, Ohio 44114-2294
(216) 771-3800



D. Peter Hochberg, Esq.
Reg. No. 24,603